

### REMARKS

This Amendment is in response to the Final Office Action mailed on February 16, 2001, which has been received and reviewed. Claims 1, 3-11, 13-44, 46, 48-64, 66-74, and 105-107 are currently pending in the application. Reconsideration of the referenced application is respectfully requested in view of the following remarks.

#### **Rejections Under 35 U.S.C. § 112, Second Paragraph**

Claims 1, 3-7, 9-11, 13-15, 18, 19, 21, 22, 25, 29, and 61 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter regarded to be the invention.

Specifically, claim 1 was objected to as use of the phrase "associated with" was deemed to be unclear. It is proposed that claim 1 be amended to recite that the at least one detector is "in communication with" at least one of the at least two porous regions of the sample separation apparatus, which should providing the clarity the Office desires. Accordingly, it is respectfully submitted that claim 1, as proposed to be amended, is in condition for allowance.

Claims 3-7, 9-11, 13-15, 18, 19, 21, 22, 25, and 29 were merely rejected for depending either directly or indirectly from claim 1.

Claim 61 was rejected under the second paragraph of section 112 because the recitation of "along a distance of at least one of said at least one sample column and said control column" "appears redundant". It is respectfully submitted that, upon closer inspection, claim 61 merely recites that the first and second electrodes, when connected to a power source, are capable of generating a current along a distance of the at least one sample column of claim 57, the control column of claim 57, or a combination of at least one sample column and the control column. Thus, it is respectfully submitted that claim 61 is not redundant or otherwise unclear. It is, therefore, respectfully requested that the rejection of claim 61 under 35 U.S.C. § 112, second paragraph, be withdrawn.

### Rejections Under 35 U.S.C. § 102

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Brothers v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

#### Isaka

Claims 1, 3, 4, 7-9, 18-20, 25, 26, 29-32, 34, 35, 38, 39, 50-52, 56, 64, 66, 69, 71, and 73 stand rejected under 35 U.S.C. § 102(b) as being inherently anticipated by U.S. Patent 5,482,598 to Isaka et al. (hereinafter "Isaka").

Claim 1 of the referenced application recites a sample separation apparatus that includes a substrate and matrices that are formed in the substrate and that comprise at least two porous regions that extend at least partially across the substrate. The sample separation apparatus of claim 1 also includes at least one detector fabricated on the substrate and associated with at least one of the at least two porous regions.

In contrast, Isaka discloses a chromatographic separation device that includes a silicon substrate and a only a single porous microchannel formed in the silicon substrate. Isaka's deficiency with respect to "at least two porous regions" is handled in the outstanding Office Action with the assertion, at page 3, that "any number of channels, i.e. two channels or columns, may be *inherently* disposed onto the microchannel element" (emphasis supplied).

With respect to the inherent anticipation of claim elements under 35 U.S.C. § 102, M.P.E.P. § 2131.01 provides:

"To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." *Continental Can Co. USA v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991) . . .

It is respectfully submitted that it is not necessary for the chromatographic separation device of Isaka to include more than the single disclosed channel. To the contrary, as Isaka discloses a

chromatographic separation device, which are well known in the art to include single separation columns or channels, it does not seem more likely that the device of Isaka would need more than a single microchannel. Since it is not necessary for the chromatographic separation device of Isaka to include more than one microchannel, Isaka cannot inherently anticipate the "at least two porous regions" required by claim 1.

Further, Isaka lacks both explicit and inherent disclosure of a detector that is fabricated on the substrate and in communication with at least one porous region formed in the substrate, as is recited in claim 1, as proposed to be amended.

For these reasons, it is respectfully submitted that Isaka does not anticipate each and every element of claim 1 and that claim 1 is, therefore, allowable under 35 U.S.C. § 102(b).

Claims 3, 4, 7-9, 18-20, 25, 26, and 29 are each allowable, among other reasons, as depending either directly or indirectly from claim 1, which should be allowed.

Again, claims 8 and 26 are each further allowable over Isaka since Isaka does not disclose an enzyme that is a capture component or capture substrate. Rather, as those of skill in the art are aware, an enzyme, such as that disclosed in Isaka, only momentarily interacts with a substrate to react with a substrate in a manner that detectably alters the substrate. Thereafter, an enzyme of the type disclosed in Isaka releases the substrate, permitting the substrate to continue migrating through a microchannel. The altered substrate is then detected upon exiting the microchannel. By way of contrast, a capture component or capture substrate of the type recited in claims 8 and 26 reacts with an analyte by capturing the analyte, preventing further migration of the analyte, and need not substantially alter the analyte.

Independent claim 30 recites a separation apparatus that includes a substrate, at least two capillary columns formed in the substrate, and a detector situated adjacent at least one of the capillary columns.

Again, Isaka does not explicitly or inherently disclose a separation apparatus with at least two capillary columns. As it is not necessary that the chromatographic separation device disclosed in Isaka include more than one microchannel, Isaka cannot inherently disclose a chromatographic separation device with at least to capillary columns. Therefore, it is respectfully

submitted that Isaka does not anticipate each and every element of claim 30. Accordingly, it is respectfully submitted that amended claim 30 is allowable under 35 U.S.C. § 102(b).

Claims 31, 32, 34, 35, 38, 39, and 50 are each allowable, among other reasons, as depending either directly or indirectly from claim 30, which should be allowed.

In addition, claim 35 is allowable since the enzyme disclosed in Isaka is not a capture component or capture substrate. Rather, as those of skill in the art are aware, an enzyme, such as that disclosed in Isaka, only momentarily interacts with a substrate to react with a substrate in a manner that detectably alters the substrate. Thereafter, an enzyme of the type disclosed in Isaka releases the substrate, permitting the substrate to continue migrating through a microchannel. The altered substrate is then detected upon exiting the microchannel. By way of contrast, a capture component or capture substrate of the type recited in claim 35 reacts with an analyte by capturing the analyte, preventing further migration of the analyte, and need not substantially alter the analyte.

Independent claim 51 recites a miniature chromatograph that includes a substrate and porous matrices formed in the substrate and comprising at least two capillary columns.

Isaka does not disclose a miniature chromatograph that includes a substrate with more than one porous matrix formed therein and at least two capillary columns formed by the porous matrices. Therefore, Isaka does not anticipate each and every element of independent claim 51. Accordingly, it is respectfully submitted that claim 51 is allowable over Isaka under 35 U.S.C. § 102(b).

Claims 52 and 56 are each allowable, among other reasons, as depending from claim 51, which should be allowed.

Independent claim 64 recites an analyte detection apparatus that includes a substrate comprising silicon. Matrices that are formed in the substrate comprise at least two porous columns that are continuous with a surface of the substrate.

Isaka does not disclose an analyte detection apparatus with more than one porous column. Therefore, Isaka does not anticipate each and every element of independent claim 64. Accordingly, it is respectfully requested that the rejection of claim 64 under 35 U.S.C. § 102(b) be withdrawn.

Claims 66, 69, 71, and 73 are each allowable, among other reasons, as depending either directly or indirectly from claim 64, which should be allowed.

Claim 66 is additionally allowable because Isaka does not disclose a capture substrate. As explained previously herein, those of skill in the art are aware that an enzyme such as that disclosed in Isaka only momentarily interacts with a substrate to react with a substrate in a manner that detectably alters the substrate. Thereafter, an enzyme of the type disclosed in Isaka releases the substrate, permitting the substrate to continue migrating through a microchannel. The altered substrate is then detected upon exiting the microchannel. By way of contrast, a capture component or capture substrate of the type recited in claim 35 reacts with an analyte by capturing the analyte, preventing further migration of the analyte, and need not substantially alter the analyte.

For the foregoing reasons, it is respectfully requested that the rejections of claims 1, 3, 4, 7-9, 18-20, 25, 26, 29-32, 34, 35, 38, 39, 50-52, 56, 64, 66, 69, 71, and 73 under 35 U.S.C. § 102(b) be withdrawn.

#### **Rejections Under 35 U.S.C. § 103(a)**

To establish a *prima facie* case of obviousness under 35 U.S.C. § 103(a), three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Third, the cited prior art reference must teach or suggest all of the claim limitations. Furthermore, the suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on Applicant's disclosure.

In addition, 35 U.S.C. § 103(c) provides:

Subject matter developed by another person, which qualifies as prior art under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Accordingly, references, such as U.S. Patent 5,885,869 to Turner et al. (hereinafter "Turner"), that qualify as prior art under 35 U.S.C. § 102(e) due to issuance after the October 23, 1998, priority date for the referenced application and that have been assigned to the same assigned as the referenced application cannot be used in a 35 U.S.C. § 103(a) rejection of any of the claims of the referenced application.

Isaka in View of Miura

Claims 14-17, 21, 40, 41, 43, 44, 54, 55, and 70 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Isaka in view of U.S. Patent 5,132,012 to Miura et al. (hereinafter "Miura").

The teachings of Isaka were summarized previously herein.

Miura discloses, among other things, a small-scale liquid chromatograph including a silicon substrate, a single, coiled column formed in the substrate, and a detector, such as a field effect transistor, formed on the substrate, adjacent the column.

Claims 14-17 and 21 are each allowable, among other reasons, as depending either directly or indirectly from claim 1, which should be allowed for the reasons provided previously herein.

Claim 16, which recites that the sample separation apparatus include a processor on the substrate, is further allowable as Miura merely teaches or suggests the possible association of a processor with the chromatograph, not that such a processor would actually be on the substrate. Further, Isaka lacks any teaching or suggestion that it would be desirable to include a processor on the substrate of the device disclosed therein. Moreover, it is respectfully submitted that since no art has been cited that demonstrates that the inclusion (not necessarily fabrication) of a processor on the substrate itself would have been an obvious design choice, that the subject matter recited in claim 16 is not obvious—otherwise, it seems as though someone would have already made that design choice.

Claim 17, which depends directly from claim 1, is additionally allowable since Isaka and Miura both lack any teaching or suggestion of a memory device on the substrate. If the inclusion of a memory device on the substrate would have been an obvious design choice, as asserted in

the outstanding Office Action, the Office is respectfully invited to cite a reference that discloses a sample separation apparatus of the type recited in claim 17 with a memory device on the substrate thereof.

Claim 21 is additionally allowable since Isaka and Miura, taken alone or in combination, both fail to teach or suggest a vacuum source in operative communication with the column of the chromatograph taught in Miura. Rather, it is Applicant's understanding that Miura only teaches or suggests the use of positive pressure to facilitate the movement of a sample through the column. *See, e.g.*, Miura, col. 10, lines 1-34.

Claims 40, 41, 43, and 44 are each allowable, among other reasons, as depending either directly or indirectly from claim 30, which should be allowed.

Claim 41 is also allowable since Isaka and Miura, taken alone or in combination, both fail to teach or suggest a vacuum source in operative communication with the column of the chromatograph taught in Miura. Rather, it is Applicant's understanding that Miura only teaches or suggests the use of positive pressure to facilitate the movement of a sample through the column. *See, e.g.*, Miura, col. 10, lines 1-34.

In addition, claim 44 is additionally allowable since neither Isaka nor Miura teaches or suggests that the chromatograph thereof includes a memory device on its substrate.

Claims 54 and 55 are each allowable, among other reasons, as depending from claim 52, which should be allowed.

Claim 70 is allowable, among other reasons, as depending from claim 64, which should be allowed.

In light of the foregoing reasons, it is respectfully requested that the Office withdraw the 35 U.S.C. § 103(a) rejections of claims 14-17, 21, 40, 41, 43, 44, 54, 55, and 70 as being rendered obvious by the combination of Isaka and Miura.

#### Isaka in View of Wang

Claims 13, 21, 41, 53, and 70 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Isaka in view of U.S. Patent 5,663,488 to Wang et al. (hereinafter "Wang").

The teachings of Isaka are discussed previously herein with respect to the 35 U.S.C. § 102 rejections asserted by the Office.

Wang teaches a thermal isolation system that includes, among other things, a chamber within which temperature and pressure may be controlled. A separation device, such as a miniature chromatographic column, may be disposed within the chamber.

Claims 13 and 21 are allowable, among other reasons, as depending from indirectly from claim 1, which should be allowed.

In addition, claim 13 is allowable since neither Isaka nor Wang, taken alone or in combination, teaches or suggests the inclusion of a thermal detector on a substrate in which the chromatography column thereof is formed. Rather, the thermal detector taught in Wang is a thermal conductivity detector that is associated with the chamber for controlling the temperature and pressure therein.

Claim 21 is further allowable since neither Isaka nor Wang, taken alone or in combination, teaches or suggests a vacuum source operatively in communication with an end of the chromatography column thereof. Rather, the vacuum of Wang, which is discussed, for example, at col. 1, line 63, to col. 2, line 4, and col. 2, lines 29-41, thereof, is used to vary the pressure within the chamber and would, therefore, be applied evenly across an entire column positioned within the chamber.

Claim 41 is allowable as depending from claim 30, which should be allowed, and further because both Isaka and Wang, taken alone or in combination, fail to teach or suggest a vacuum source operatively in communication with an end of a chromatography column.

Claim 53 is allowable as depending from claim 52, and also since Isaka and Wang, taken alone or in combination, lack any teaching or suggestion of the inclusion of a thermal detector on a substrate in which the chromatography column is formed.

Claim 70 is allowable as depending from claim 64, and also because neither Isaka nor Wang teaches nor suggests the inclusion of a thermal detector, a field effect transistor, or a current detector on a substrate in which the chromatography column is formed.



For the foregoing reasons, it is respectfully requested that the Office withdraw the 35 U.S.C. § 103(a) rejections of claims 13, 21, 41, 53, and 70 as being unpatentable in view of the teachings of Isaka and Wang.

Isaka in View of Turner

Claims 33, 74, and 105-107 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Isaka in view of U.S. Patent 5,885,869 to Turner et al. (hereinafter "Turner").

The referenced application, which is a Continued Prosecution Application of U.S. Ser. No. 09/177,814, was filed on April 18, 2000. Thus, the provisions of 35 U.S.C. § 103(c) apply.

The referenced application is entitled to priority, under 35 U.S.C. § 120, of the October 23, 1998, filing date of U.S. Ser. No. 09/177,814. Accordingly, Turner, which did not issue until March 23, 1999, and which is owned by Micron Technology, Inc., to which the referenced application has also been assigned, qualifies as prior art under 35 U.S.C. § 102(e). Accordingly, Isaka and Turner cannot be properly combined under 35 U.S.C. § 103(a) to render the subject matter recited in any of the claims of the referenced application obvious.

35 U.S.C. § 103(c).

Therefore, it is respectfully requested that the Office withdraw the 35 U.S.C. § 103(a) rejections of claims 33, 74, and 105-107 as being rendered unpatentable by the combination of Isaka and Turner.

Isaka or Northrup in View of Turner and Further in View of Sunzeri and Swedberg

Claims 5, 6, 10, 11, 27, 28, 36-38, 45-49, 57-63, 67, 68, and 72 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Isaka or, if necessary, Northrup in view of Turner and in further view of U.S. Patent 5,536,382 to Sunzeri (hereinafter "Sunzeri") and U.S. Patent 5,571,410 to Swedberg et al. (hereinafter "Swedberg").

Again, the referenced application, which is a Continued Prosecution Application of U.S. Ser. No. 09/177,814, was filed on April 18, 2000. Thus, the provisions of 35 U.S.C. § 103(c) apply.

The referenced application is entitled to priority, under 35 U.S.C. § 120, of the October 23, 1998, filing date of U.S. Ser. No. 09/177,814. Accordingly, Turner, which did not issue until March 23, 1999, and which is owned by Micron Technology, Inc., to which the referenced application has also been assigned, qualifies as prior art under 35 U.S.C. § 102(e). Accordingly, Turner cannot be properly combined under 35 U.S.C. § 103(a) with any other references (i.e., either Isaka or Northrup in view of Sunzeri and Swedberg) to render the subject matter recited in any of the claims of the referenced application obvious. 35 U.S.C. § 103(c). Therefore, it is respectfully requested that the Office withdraw the 35 U.S.C. § 103(a) rejections of claims 5, 6, 10, 11, 27, 28, 36-38, 45-49, 57-63, 67, 68, and 72 as being rendered unpatentable by either Isaka or Northrup in view of Turner, and further in view of Sunzeri and Swedberg.

Isaka in View of Northrup

Claims 22-24 and 42 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Isaka in view of Northrup.

Claims 22-24 are each allowable, among other reasons, as depending from claim 1, which should be allowed.

Claim 42 is allowable, among other reasons, as depending from claim 30, which should be allowed.

In view of the foregoing, it is respectfully requested that the 35 U.S.C. § 103(a) rejections of claims 5-6, 10-11, 13-17, 21-24, 27-28, 33, 36-38, 40-49, 53-55, 57-63, 67-68, 70, 72, 74, and 105-107 be withdrawn.

### CONCLUSION

It is respectfully submitted that claims 1, 3-11, 13-44, 46, 48-64, 66-74, and 105-107 are in condition for allowance. An early indication of such and that the case be passed for issue are respectfully solicited. If any issues preventing the allowance of any of these claims that may be resolved by a telephone conference remain, the Office is respectfully invited to contact the undersigned at the telephone number provided below.

Respectfully submitted,



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Enclosure: VERSION WITH MARKINGS TO SHOW CHANGES MADE

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**VERSION WITH MARKINGS TO SHOW CHANGES MADE****IN THE CLAIMS:**

1. (Amended four times) A sample separation apparatus, comprising:  
a substrate comprising at least one of silicon, gallium arsenide, and indium phosphide; [and]  
matrices formed in said substrate, said matrices comprising at least two porous regions, each of  
said at least two porous regions extending at least partially across said substrate; and  
at least one detector fabricated on said substrate [and associated] in communication with at least  
one of said at least two porous regions.